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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,256	04/08/2004	Robbert Benner	3077-6420US	1851

24247 7590 10/23/2006

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EXAMINER	
KIM, YUNSOO	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 10/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/821,256	BENNER ET AL.	
	Examiner	Art Unit	
	Yunsoo Kim	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 10-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,10-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/21/06,8/1/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-8 and 10-13 are pending.

2. Applicants' IDS filed on 4/21/06 and 8/1/06 have been acknowledged.

3. Applicants' submission of newly executed oath dated 8/1/06 has been acknowledged.

4. In view of Applicant's amendments to the specification and claims and responses filed 8/1/06, the following rejections remain.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-7 and 10-13 stand rejected under 35 U.S.C. 102(b) as being anticipated by WO 01/72831 (IDS reference, of record) as evidenced by Merck Index (17th ed. 1999, p. 1145-1146, 1841-1848, 2539, 2550, of record) and Dwinnell et al. (Atlas of Diseases of the Kidney, Ch. 12, 1999), newly cited, for the reasons set forth in the office action mailed 3/2/06.

The '831 publication teaches a method of treating septic shock by administration of synthetic immunoregulator AQGV in a patient (p 3-4, 18, 22, 27, 44, 55, 61, claims 3, 13, 22-25, in particular). The '831 publication further teaches the administration of the immunoregulator intraperitoneally in PBS (p. 39, in particular). As cardiac ischemia reperfusion was performed in coronary artery occlusion model (p. 53, 66, in particular), renal ischemia reperfusion test is included for diagnostic process for renal failure.

As is evidenced in Merck Index, p. 1145-46, septic shock causes acute renal failure and the blood urea concentration is increased as result of renal failure. Treating septic shock results lowering blood urea nitrogen concentration. Furthermore, the Merck Index teaches major causes for acute renal failure being septic shock (p. 1842, table, in particular), patient with oliguria has increased blood urea nitrogen in serum (p. 1145, 1847, table, in particular), decreased secretion of urine compared to 1-2.4L/day comparable to less than 0.5ml/kg/hr (p. 1145, 1842, in particular), increased potassium (p. 2539, in normal being 3.5 -5.3mmol/L) and maintain at 6 mmol/L (p. 1845, in particular) as indication, symptoms and signs of renal failure.

Applicants' arguments filed on 8/1/06 have been fully considered but they are not persuasive.

Applicants argue that the prior art reference is not sufficient to establish the inherency of the result and it was not certain that the renal failure will definitely cause the increase of blood urea nitrogen concentration.

As it is well known in the art and is further evidenced by the Dwinnell reference, the acute renal failure is defined as " abrupt deterioration of renal function sufficient to result in failure of urinary elimination of nitrogenous waste products (urea nitrogen and creatine), (p. 12.1, in particular). Dwinnell et al. further teaches that the deterioration of renal function results in elevation of blood urea nitrogen and serum creatine concentrations (p. 12.1, in particular).

The '831 publication also teaches the oligopeptide composition is useful in treating the various renal diseases (p. 19, in particular). Thus, reducing blood urea nitrogen concentration is inherent property of the oligopeptide composition consisting of SEQ ID NO:2. Thus, reference teachings anticipate the claimed invention.

7. Claims 1-5, 7, 8 and 10-13 stand rejected under 35 U.S.C. 102(e) as being anticipated by 2004/0013661 (IDS reference, of record) as evidenced by Merck Index (17th ed. 1999, p. 1145-1146, 1841-1848, 2539, 2550, of record), Merriam Webster's Dictionary (p. 82, of record) and Dwinnell et al. (Atlas of Diseases of the Kidney, Ch. 12, 1999), newly cited for the reasons set forth in the office action mailed 3/2/06.

The '661 publication teaches a method of treating sepsis including bacterial infection (e.g. septic shock) or ischemia reperfusion injury by administration of pharmaceutical composition comprising synthetic immunoregulator AQGV in bolus (e.g. orally) or infusion (parenterally) with dose of 1-5 mg/kg bodyweight (abstract, claim 1, [0021-23], [0043-45], [0050], in particular).

The '661 publication further teaches use of combination of immunoregulator ([0048]), use of diagnostic process to determine disease stage (claim 1) and septic shock causes multiple organ failure (e.g. renal failure, [0021], in particular).

As is evidenced in Merck Index, p. 1145-46, septic shock causes acute renal failure and the blood urea concentration is increased as result of renal failure. Treating septic shock results lowering blood urea nitrogen concentration. Furthermore, the Merck Index teaches major causes for acute renal failure being septic shock (p. 1842, table, in particular), patient with oliguria has increased blood urea nitrogen in serum (p. 1145, 1847, table, in particular), decreased secretion of urine compared to 1-2.4L/day comparable to less than 0.5ml/kg/hr (p. 1145, 1842, in particular), increased potassium (p. 2539, in normal being 3.5 -5.3mmol/L) and maintain at 6 mmol/L (p. 1845, in particular) as indication, symptoms and signs of renal failure.

"Bolus" is defined in Merriam-Webster's Medical Desk Dictionary as a rounded mass, soft mass of chewed food, thus it is extended to include oral administration.

Reducing blood urea nitrogen concentration is inherent property of the oligopeptide composition consisting of SEQ ID NO:2. Thus, reference teachings anticipate the claimed invention.

Applicants' arguments filed on 8/1/06 have been fully considered but they are not persuasive.

Applicants argue that the prior art reference is not sufficient to establish the inherency of the result and it was not certain that the renal failure will definitely cause the increase of blood urea nitrogen concentration.

In light of the discussion above, reducing blood urea nitrogen concentration is inherent property of the oligopeptide composition consisting of SEQ ID NO:2. Thus, reference teachings anticipate the claimed invention.

8. The following new ground of rejection is necessitated by the Applicants' amendment filed 8/1/06.

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1-8 and 10-13 are provisionally rejected under the judicially created doctrine of obvious-type double patenting as being unpatentable over claims 1-13 of U.S.Applic. No. 11/249,541.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a method of reducing blood urea nitrogen concentration with a olipopeptide comprising a sequences of AQG or MTRV.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. No claims are allowable.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on Monday thru Friday 8:30 - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Yunsoo Kim
Patent Examiner
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October 10, 2006

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